

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 7

11201 Renner Boulevard Lenexa, Kansas 66219

SENT VIA ELECTRONIC MAIL RECEIPT CONFIRMATION REQUESTED

Ex. 4 CBI

Re: Request to Substantiate Claim of Confidentiality AltEn, LLC, Mead, Nebraska

Dear Ex. 4 CBI:

The U.S. Environmental Protection Agency ("EPA") is seeking to determine the entitlement to confidentiality of the information you submitted to the EPA. AltEn submitted a confidentiality claim over the information submitted on February 24, 2021 and April 27, 2021, in response to EPA's information requests dated February 16, 2021 and April 12, 2021. You have claimed all of this information as confidential business information ("CBI").

The purpose of this letter is to notify you that the EPA Region 7 Office of Regional Counsel will be making an advance confidentiality determination concerning the information you have claimed as CBI. If you feel that some or all of the information is entitled to confidential treatment, you must make the showings below with specific reference to those portions of the information you consider confidential.

Please be specific by page (including Bates Stamp, if applicable), paragraph, and sentence when identifying and substantiating the information subject to your claim. Where your claim, as originally made or as modified by your response to this letter, does not include all information on a page, please attach a copy of each such page with brackets around the text that you claim to be CBI. Please note that if a page, document, group, or class of documents claimed by you to be CBI contains a significant amount of information which the Office of General Counsel determines is not CBI, your CBI claim regarding that page, document, group, or class of documents may be denied. Any information not specifically identified as subject to a confidentiality claim and substantiated as such in your response to this letter may be disclosed to the requester without further notice to you.

In making its final confidentiality determination, the EPA will consider the relevant substantive criteria in its CBI regulations, under 40 C.F.R. § 2.208(a)-(d), as well as the U.S. Supreme Court's decision in *Food Marketing Institute v. Argus Leader Media (Argus)*, 139 S. Ct.

2356 (2019), which evaluated the definition of "confidential" as used in Exemption 4. In the *Argus* decision, the Court held that at least where "[1] commercial or financial information is both customarily and actually treated as private by its owner and [2] provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." *Argus*, 139 S. Ct. at 2366.

Thus, for each item or class of information that you claim as CBI, please answer the following questions, giving as much detail as possible. EPA will use your responses to these questions to determine whether the information has been shown to be entitled to confidential treatment:

Questions 1-7 must be answered with respect to any confidentiality claims pertaining to the enclosed product chemistry information.

- 1. What value can your competitors derive from knowing the identity, percent by weight, certified limits, or parent process of each impurity? Is this impurity unique to your manufacturing process? Why would your competitors find this impurity preferable over whatever impurity results from their equivalent process?
- 2. Does published analytical methodology exist that could identify and quantify this impurity? If so, why do you believe that your competitors have not already performed such analysis?
- 3. What value can your competitors derive from knowing the description of materials used to produce the product, the description of the production process, or the preliminary production analysis? Why would your competitors find these processes preferable over their equivalent processes?

Questions 4-7 must be answered with respect to any confidentiality claims pertaining to the inert ingredients. Each question must be answered separately with respect to each inert ingredient:

- 4. What is the value that this inert ingredient brings to the product formulation? What characteristics of this ingredient are unique such that competitors might prefer it over whatever ingredients perform the equivalent function in their formulations? Is the use of this ingredient limited to your product, or does it have broader applications?
- 5. Why is it unlikely that your competitors have not already discovered the value of this ingredient? Are you aware of the use of this ingredient as an inert by your competitors?
- 6. To your knowledge, has the use of this inert ingredient in a pesticide been disclosed in a patent? If so, how would disclosure of the identity of the ingredient assist your competitors beyond what is already available through a patent?
- 7. Can the identity of this inert ingredient be determined by product sample analysis? If so, why do you believe that your competitors have not already performed such analysis?

Questions 8 through 17 must be answered for each type of information that you claimed as confidential:

- 8. For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.
- 9. Information submitted to the EPA becomes stale over time. Please explain why EPA should protect the information you claim as confidential for the time period specified in your answer to question #1.
- 10. Has EPA, another federal agency, or court made any determination as to the confidentiality of the information? If so, please attach a copy of the determination.
- 11. Is the information contained in any publicly available material such as patents or patent applications, publicly available databases (including state databases), promotional publications, annual reports, or articles? Yes/No
 - If you answered "yes", please identify the publicly available information and its location (e.g., patent number or website address).
- 12. Has your company taken reasonable measures to protect the information claimed as CBI? If so, please identify the measure or internal controls your business has taken to protect the information claimed as confidential:
 - a. Non-disclosure agreement required prior to access. Yes/No
 - b. Access is limited to individuals with a need-to-know. Yes/No
 - c. Information is physically secured (e.g. locked in a room or cabinet) or electronically secured (encrypted, password protected, etc.). Yes/No
 - d. Other internal control measures(s). Yes/No. (If yes, please explain.)
- 13. Does your company customarily keep the information private or closely-held? If so, please explain the basis for your response.
- 14. At the time you submitted the information you claimed as CBI, did EPA provide any express or implied assurance of confidentiality? If so, please explain the specific assurance(s) you received. For example, expressed assurances indicating that information will not be publicly disclosed could include legal authorities (regulation or statute), direct communications, class determinations, etc. Examples of implicit assurances could include a description of the specific context in which the information was received.
- 15. Did the Agency provide any expressed or implied indications at the time the information was submitted that EPA would publicly disclose the information?

- 16. If you believe any submitted information to be a trade secret, please state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be a trade secret.
- 17. Explain any other issue or additional information you deem relevant to EPA's determination.

Please note that you bear the burden of substantiating your CBI and trade secret claim(s). Generalized or conclusory statements will be given little or no weight in EPA's determination on the confidentiality of the information you claim to be CBI. Be advised that information described by Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") section 10(d)(l)(A), (B), and (C) is not automatically entitled to confidential treatment. Disclosure of such information would only be prohibited, by FIFRA section (b), if the information is eligible for confidential treatment as described by 40 CFR 2.208(a)-(d).

Your comments must be postmarked or hand delivered to this office, or emailed to stillwagon.angela@epa.gov, by the 15th working day after your receipt of this letter. You may seek an extension of time to submit your comments to this office, but your request must be made before the end of the 15-day period. Except in extraordinary circumstances, no extension will be approved without the consent of the FOIA requester. Failure to submit your comments within that time will be regarded as a waiver of your confidentiality claim(s), and the EPA may release the information.

If you wish to claim any information that you provide in your response to this letter to be claimed as CBI, you must mark the response with "CONFIDENTIAL BUSINESS INFORMATION" or with a similar designation, and you must bracket all text in the response that you so claim. Information so designated will be disclosed by the EPA only to the extent allowed by, and by means of the procedures set forth in, 40 C.F.R. Part 2, Subpart B. If you fail to claim the information provided in your response as confidential, it may be made available to the public without further notice to you.

Should you have any questions concerning this matter, please call me at 913-551-7707.

Sincerely,

Stillwagon, Angela Digitally signed by Stillwagon, Angela Date: 2021.11.30 09:53:43 -06'00'

Angela Stillwagon Attorney Office of Regional Counsel